CHAPTER 166

CLASSICAL SWINE FEVER VIRUS AND SERUM

Referred to in §159.6

166.1 Definitions.

When used in this chapter:

1. *"Biological products"* shall include and be deemed to embrace only anti-classical swine fever serum and viruses which are either virulent or nonvirulent, alive or dead.

2. *"Dealer"* includes every person who, for profit, sells, dispenses, or distributes, or offers to do so, either as principal or agent, biological products, except:

a. A manufacturer selling direct to any person licensed under this chapter to sell, dispense, or distribute such biological products.

b. A regularly licensed veterinarian who uses such biological products in the veterinarian's professional practice and does not use it for sale or distribution to any other person.

3. *"Department"* means the department of agriculture and land stewardship.

4. *"Manufacturer"* includes every person engaged in the preparation, at any stage of the process, of biological products, except those engaged in such preparation in any state or governmental institution.

5. *"Place of business"* is construed to mean each place or premises where biological products are sold, or where biological products are stored or kept for the purpose of sale, dispensation or distribution, or where biological products are offered for sale, dispensation or distribution.

6. *"Secretary"* means the secretary of agriculture.

[SS15, §2538-w12; C24, 27, 31, 35, 39, §**2705;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.1]

2005 Acts, ch 19, §34; 2012 Acts, ch 1095, §36; 2017 Acts, ch 159, §23

Further definitions; see §159.1

166.2 Rules.

The department shall have power to make such rules governing the manufacture, sale, and distribution of biological products as it deems necessary to maintain their potency and purity.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2706;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.2]

166.3 Permit to manufacture or sell.

Every person, before engaging as a manufacturer of, or dealer in, biological products shall obtain from the department a permit for that purpose and shall be required to have a separate

permit for each place of business. A pharmacy licensed under chapter 155A shall not be required to obtain a dealer's permit to deal in biological products.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2707;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.3]

87 Acts, ch 215, §42

166.4 Application for permit.

Every application for such a permit shall be made on a form provided by the department, which form shall call for such information as the department shall deem necessary, including the name and place of business of the applicant.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2708;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.4]

166.5 Manufacturer's permit.

An application for a permit to manufacture biological products shall be accompanied by evidence satisfactory to the department that the applicant is the holder of a valid, unrevoked, United States department of agriculture license for the manufacture and sale of such biological products.

[C24, 27, 31, 35, 39, §**2709;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.5]

166.6 Dealer's permit.

An application for a permit to deal in biological products shall be accompanied by a separate bond for each place of business, with sureties to be approved by the department, in the sum of five thousand dollars for each place of business, which bond shall be conditioned:

1. To faithfully comply with all laws governing the warehousing, sale, and distribution of biological products, and with all the rules of the department relating to such biological products.
2. To indemnify any person who uses any such biological products sold by the principal and is damaged by the negligence of the principal, or any of the principal's agents, in the warehousing, handling, sale, or distribution of such biological products.
3. To pay to the state all penalties which may be adjudged against the principal.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2710;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.6]

99 Acts, ch 114, §10

166.7 Liability on bond.

The principal on such bond shall be liable to every person for any damage caused by the negligence of the principal or of the principal's agents, notwithstanding the execution of the bond.

[C24, 27, 31, 35, 39, §**2711;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.7]

166.8 New or additional bond.

When judgment is rendered on such bond, the principal shall immediately execute and file with the department a new or additional bond, conditioned as the original bond, and in an amount to be fixed by the department, which will furnish the same amount of security that was furnished before the original bond was impaired.

[C24, 27, 31, 35, 39, §**2712;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.8]

166.9 Liability of manufacturer.

A manufacturer shall be liable to an injured person for all damages which occur:

1. By reason of the negligence of the manufacturer or the manufacturer's employees in the manufacture, warehousing, handling, or distribution of biological products.
2. By reason of the failure of the manufacturer, or the manufacturer's employees, to discharge any duty imposed by law, or by the rules of the department.

[C24, 27, 31, 35, 39, §**2713;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.9]

166.10 Fees.

Fees for permits shall be paid by the manufacturer or dealer to the department when the application for such permit is made and shall be:

1. In case of a manufacturer, twenty-five dollars for each plant at which it is proposed to manufacture biological products.

2. In case of a dealer, five dollars for each place of business, warehouse or distributing agency of the dealer.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2714;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.10]

166.11 Inspection of premises.

The premises upon which the business authorized by such permit is carried on shall be subject at all times to inspection by the department. Before issuing an original permit, the department may cause the proposed premises to be inspected, and shall make such requirements regarding the physical conditions and sanitation of said premises as it may deem necessary to secure and maintain the potency and purity of the biological products. If such requirements are not complied with and maintained, the permit shall be refused or revoked as the case may be.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2715;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.11]

166.12 Manufacturer's or dealer's permit.

Every permit issued to a manufacturer or dealer shall expire on the first day of July following the date of issuance. A renewal of the same shall be subject to all the conditions, including fees, that are required in the case of an original permit.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2716;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.12]

166.13 Revocation of permit.

Such a permit shall be automatically revoked:

1. In case of a dealer, by the dealer's failure to execute and file with the department a new and approved bond when required by law, or by the dealer's failure to obtain a separate permit and to file a separate bond in the amount of five thousand dollars for each place of business.

2. In case of a manufacturer, by the manufacturer's ceasing to be the holder of a United States department of agriculture license for the manufacture and sale of biological products.

3. In case of either a manufacturer or dealer, for discrimination in the price at which such biological products are sold, and such permit shall not in such case be renewed for one year.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2717;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.13]

166.14 Revocation by department.

Such a permit may also be revoked by the department at any time after a reasonable notice and hearing:

1. For violation of the terms, conditions, and requirements on which it was issued.

2. For violation of any law, or of any rule of the department, relating to the business authorized by such permit.

3. In case of a dealer's permit, when a judgment has been rendered on the bond, or when the security of such bond has become impaired in any other way and no new bond is given as required by the department.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2718;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.14]

166.15 Prohibited sales.

No biological products shall be sold, offered for sale, distributed, or used, unless produced at a plant which, at the time of producing, held a United States department of agriculture license for the manufacture of such biological products.

[SS15, §2538-w3; C24, 27, 31, 35, 39, §**2719;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.15]

166.16 Sales — limitation.

A person shall not sell, distribute, use, or offer to sell, distribute, or use virulent blood or virus from classical-swine-fever-infected swine except for one or more of the following purposes:

1. For the purpose of interstate or foreign shipment of such blood or virus.
2. For the purpose of research at any biological laboratory or by any manufacturer of biological products.
3. For the purpose of testing biological products by any governmental authority or by any manufacturer of biological products.
4. For the purpose of manufacturing any biological products or for the purpose of producing immune swine to be used in the production of anti-classical swine fever serum.

[SS15, §2538-w5; C24, 27, 31, 35, 39, §**2720;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.16]

2012 Acts, ch 1095, §37, 38
Referred to in §166.41

166.17 through 166.28 Reserved.

166.29 Reports by manufacturers and dealers.

A person holding a permit as manufacturer or dealer shall make such written reports to the department relative to biological products as it may from time to time require.

[SS15, §2538-w5; C24, 27, 31, 35, 39, §**2733;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.29]

166.30 through 166.33 Reserved.

166.34 Seizure of samples.

The department may seize, at any time or place, for examination, samples of biological products manufactured or kept for use or sale within the state.

[S13, §2538-w6; C24, 27, 31, 35, 39, §**2738;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.34]

166.35 Condemnation and destruction.

The department shall have power to condemn and destroy any biological products which it deems unsafe.

[S13, §2538-w6; C24, 27, 31, 35, 39, §**2739;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.35]

166.36 Defacing labels.

No person shall remove or deface any label upon the bottles or packages containing any biological products or change the contents from the original container except for immediate use.

[SS15, §2538-w8; C24, 27, 31, 35, 39, §**2740;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.36]

166.37 Price of virus.

Persons holding permits, either as manufacturers or dealers, shall sell all biological products at a uniform price to all persons to whom sales are made. No rebate on said price shall be given, either directly or indirectly, in any manner whatsoever.

[C24, 27, 31, 35, 39, §**2741;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.37]

166.38 Compensation.

No licensed veterinarian shall receive, directly or indirectly, any compensation of any kind for the handling, sale, or use of any biological products, other than the veterinarian's charges for administering the same, unless the veterinarian makes known in writing the amount of such compensation, if requested to do so by the person using biological products. Any veterinarian violating this section shall be guilty of a simple misdemeanor.

[C24, 27, 31, 35, 39, §**2742;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.38]

Revocation of license, §169.13

166.39 Violations.

Any person who violates any provision of this chapter, or any rule of the department, or who shall hinder or attempt to hinder the department or any duly authorized agent or official thereof in the discharge of that person's duty, shall be fined in a sum not less than one hundred dollars nor more than five hundred dollars.

[S13, §2538-w7; C24, 27, 31, 35, 39, §**2743;** C46, 50, 54, 58, 62, 66, 71, 73, 75, 77, 79, 81, §166.39]

166.40 Reserved.

166.41 Classical swine fever vaccine prohibited — emergency.

The sale or use of classical swine fever vaccine, except as provided in section 166.16, is prohibited and a person shall not use such a product in this state. However, in the case of an emergency as defined in section 166.42, a special permit for the use of vaccines may be issued by the secretary.

[C66, 71, 73, 75, 77, 79, 81, §166.41]

2012 Acts, ch 1095, §39

166.42 Biological products reserve — use.

1. The secretary may establish a reserve supply of biological products of approved modified live virus classical swine fever vaccine and of anti-classical swine fever serum or its equivalent in antibody concentrate to be used as directed by the secretary in the event of an emergency resulting from a classical swine fever outbreak. Vaccine and serum or antibody concentrate from the reserve supply, if used for such an emergency, shall be made available to swine producers at a price which will not result in a profit. Payment shall be made by the producer to the department and such vaccine shall be administered by a licensed practicing veterinarian. The secretary may cooperate with other states in the accumulation, maintenance and disbursement of such reserve supply of biological products. The secretary, with the advice and written consent of the state veterinarian, and the advice and written consent of the veterinarian-in-charge for Iowa of the animal and plant health inspection service — veterinary services, United States department of agriculture, shall determine when an emergency resulting from a classical swine fever outbreak exists.

2. The secretary is authorized to sell or otherwise dispose of classical swine fever vaccine or serum if the potency of such vaccine or serum is in doubt. Moneys received under provisions of this section shall be paid into the state treasury.

[C71, 73, 75, 77, 79, 81, §166.42]

99 Acts, ch 96, §17; 2000 Acts, ch 1058, §21; 2012 Acts, ch 1095, §40; 2017 Acts, ch 159, §24; 2019 Acts, ch 24, §104

Referred to in §166.41